

Possible reforms of the authorisation procedure for animal experiments in Switzerland

Discussion paper of the Ethics Committee for Animal Experimentation (ECAE)

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Executive Summary

Animal experiments, representing an integral part of science, require official authorisation. The purpose of the authorisation procedure is to ensure compliance with legal requirements and, where justified, to approve applications for animal experiments. The procedure is exposed to significant criticism voiced by various parties and on diverse grounds, jeopardising, ultimately, both scientific progress and the legitimacy of animal experiments. These developments pose challenges for researchers and licensing authorities alike, and hamper the authorisation procedure as such.

Against this background, the Ethics Committee for Animal Experimentation (ECAE) of the Swiss Academies of Arts and Sciences organised a roundtable in autumn 2021, to shed light on the authorisation procedure from the perspective of various stakeholders. These expressed criticism about the existing processes and criteria applied in the authorisation procedure, the lack of harmonisation and transparency, insufficient expertise in animal experimentation committees (AECs), inadequate quality assurance of institutions conducting research, deficiencies in applications, the use of unclear and arbitrary evaluation criteria, a lack of communication between applicants and licensing authorities, and a lack of resources at all stages of the procedure. Different viewpoints and emphases aside, a consensus emerged among the participants of the roundtable, namely that there is an urgent need to harmonise the criteria and processes of the authorisation procedure.

Based on this roundtable, the ECAE set itself the goal of developing proposals for process-oriented reforms – inspired by reforms of the authorisation procedure in human research centred on harmonisation and professionalisation. In the present discussion paper, the ECAE outlines the weaknesses in current enforcement practice, identifies promising measures – at the example of human research – and on this basis presents proposals for possible reforms of the authorisation procedure for animal experiments in Switzerland. The aim of this paper is to launch a broad discussion among the relevant stakeholders (incl. researchers, institutions conducting animal experiments, AEC members, cantonal and federal authorities, academia, animal protection organisations etc.) about possible reforms of the procedures. Key propositions are summarised in this Executive Summary for the second roundtable, the ultimate goal of which is to explore whether (and why or why not) stakeholders can agree on certain reform proposals.

Proposals for institutional reforms

Harmonisation through the establishment of an umbrella association of cantonal animal experimentation committees (AECs):

The foundation of the umbrella organisation swissethics played a key role in harmonizing ethical evaluation in human research. Similarly, the creation of an intercantonal association, swissanimaethics (SAE), could be envisaged to improve the situation in the area of animal experimentation. This AEC umbrella organisation could be tasked to coordinate and harmonise the processes, standards and criteria applied in the review of applications for animal experiments, to organize and provide training and continuing education of AEC members, and to represent AECs vis-à-vis external stakeholders.

Reorganisation of AECs: AECs could be structurally reorganized to pool and expand the technical expertise of the approval authorities and streamline administration. The ECAE is proposing four alternative models for discussion, all of which could operate alongside the SAE:

- a **decentralised model**, that, as before, provides for several (but fewer overall) cantonal or regional AECs. Advantages of this model would be preserving existing structures and respecting local conditions. The disadvantages include the high demand for specialists to ensure the requisite expertise in all AECs and a considerable need for harmonisation.
- a **decentralised-hierarchical model** that provides for a hierarchical structure with cantonal or regional AECs and a central AEC that would be responsible, for example, for particularly serious experiments and controversial animal experiment applications. The advantages of this model include reducing the time and technical pressures on AECs and ensuring uniform decision-making practice for particularly critical applications. Disadvantages include the additional need for coordination between the central and the cantonal or regional AECs and the risk of increasing involvement of the central AEC.
- a **centralised model** that provides for a single central AEC as the sole licensing authority. The advantages of this model include easier recruitment of a sufficiently large pool of committee members with broad expertise, uniform processes, standards and criteria for evaluation, and a considerably leaner administration. Disadvantage would be the decoupling of local conditions and cantonal tasks relating to control and monitoring of animal experiments and research facilities.
- a **centralised-thematic model** which, like the centralized model, provides for national pooling of funding authorities, but separates them according to research topics (e.g. cancer research, infectious diseases, neurosciences, etc.) or areas of application (e.g. basic research, regulatory animal testing, etc.). The primary advantage of this model would be to ensure relevant disciplinary expertise. Disadvantages include additional structural complexity and a substantial need for coordination and harmonisation.

Improvement of quality management at research institutions: Strengthening scientific quality management was a key element in reforming the authorisation procedure for human research. To ensure scientific quality and compliance with legal standards in animal experiments, and to alleviate pressure on the AECs reviewing applications for such experiments, quality management could be appropriately strengthened at institutions conducting research. Possible models for this could be, following the Anglo-American pattern, internal Animal Welfare Ethical Review Bodies (AWERBs) or Institutional Animal Care and Use Committees (IACUCs) for animal experiments, or the Clinical Trial Units (CTUs) established for clinical trials in human research. These could be established on the basis of existing structures (animal welfare officers, 3R coordinators, study planning and statistics advisors, internal peer review).

Proposals for procedural reforms

Increasing the number of AEC members: Given the great diversity of research projects and the wide variety of expertise required in reviewing applications for animal experiments, reinforcing AECs with additional members with relevant expertise could be considered. This could be substantially facilitated by reorganising the AECs according to the above-mentioned models.

Focusing of tasks and reducing the burden on AECs: The decision-making process of the licensing authorities currently focuses on reviewing scientific methods (suitability) and implementation of the 3Rs (necessity), and thus on assessing instrumental indispensability. To ensure a more in-depth consideration of the weighing of interests to assess final indispensability, the AECs could be relieved of some of the burden of assessing instrumental indispensability. This could be achieved, for example, through improved quality management on the part of institutions conducting research, a more suitable application form for animal experiments, direct communication between applicants and AEC members, and creating a scientific office to review applications for formal and substantive correctness.

Strengthening of scientific expertise in the review process: Greater involvement of scientific expertise could facilitate the assessment of instrumental indispensability, e.g. through peer reviews, establishing nationally recognised Standard Operating Procedures (SOPs) and evidence-based guidelines on severity. In addition, a central pool of external experts could support AECs in assessing animal experiment applications for instrumental indispensability, thereby reducing the number of queries to applicants.

Objective rules on recusal and transparent decision-making processes: Rules for recusal serve to protect applicants and their claim to equal and fair treatment, and to ensure public confidence in the authorisation procedure. Similar to the regulations in the field of human research, uniform, objective grounds for bias could be defined and the interests of all AEC members disclosed. Centralised models could minimise the risk of recusal compared to decentralised models. To promote extensive transparency, anonymised minutes of meetings could be made available to applicants, and the interested public upon request.

Specific training and continuing education: At present, new members of AECs attend a one-day introductory course and continuing education of one day per year. However, the continuing education is not specifically geared to the work of the AECs, but covers all events relevant to animal experiments. AEC members (and, possibly, employees of the scientific offices) could receive more targeted training and continuing education, particularly with regard to the scientific, ethical and legal requirements for application review.

Adequate compensation for committee members: The compensation of AEC members varies widely. In some cantons, members receive symbolic rather than adequate compensation for their work. In this regard, an inventory of the cantonal differences in remuneration and an in-depth discussion on appropriate compensation for AEC members could be considered.

Optimisation of the procedure's duration and processes and of the period of authorisation: A frequent criticism from researchers is the lack of reliability of deadlines for the review of applications and the generally long duration of the procedure. One way to improve legal and planning certainty would be to set uniform processing deadlines and ensure they are strictly adhered to. The above-mentioned reform proposals for restructuring licensing authorities and for increasing the number of AECs whilst reducing their workload could facilitate this. In addition, in the field of human research, direct communication between the committees and applicants has

proved helpful in reducing processing times. Since numerous research projects run for a period of 4 years (e.g. SNSF) or even 5 years (e.g. ERC), harmonisation of the period of authorisation with the project duration could also be considered.